



English

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

Sinulex® Forte Capsules

Strength

391.81 mg per capsule

Pharmaceutical form

Capsule, hard gelatin, solid oral

Active substances

| | |
|---------------------------------|---------|
| Vitamin C | 300 mg |
| Horseradish root | 50 mg |
| Zinc sulfate heptahydrate | 21.8 mg |
| Pelargonium root | 20 mg |
| Vitamin D3 | 7.5 µg |

Sugar-free:

- Does not contain sweeteners.

This product is Complementary Medicine (Category D33.7); and is identified according to its discipline as a Combination Product; which is not registered by the Authority.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety, or intended use.

Read all of this leaflet carefully because it contains important information for you

Sinulex® Forte Capsules is available without a doctor's prescription, for you to treat a mild illness or maintain your health. Nevertheless, you still need to use Sinulex® Forte Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Sinulex® Forte Capsules with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What Sinulex® Forte Capsules is and what it is used for.
2. What you need to know before you use Sinulex® Forte Capsules.
3. How to take Sinulex® Forte Capsules.
4. Possible side effects.
5. How to store Sinulex® Forte Capsules.
6. Contents of the pack and other information.

1. What Sinulex® Forte Capsules is and what it is used for.

Sinulex® Forte Capsules support the immune system to deal with allergens, colds, flu, and sinusitis for better overall health. Due to the active substances, Sinulex® Forte Capsules are indicated for therapeutic use only from the age of 6 years and older. These active substances are useful for symptomatic relief of sinus pressure, sinus congestion, post-nasal drip, colds, and flu symptoms, by supporting the respiratory and immune systems. Its active substances may also support the immune function of those who are asymptomatic as a low-risk health supplement and can be used to maintain healthy levels of Vitamin C, Vitamin D3, and Zinc. It is a health supplement that contains important immunomodulator and immunostimulant properties and can be used to support the respiratory tract, supporting the paranasal sinuses. Sinulex® Forte Capsules are indicated for self-administration as a low-risk health supplement, although only a healthcare provider may indicate it as an adjunct treatment to an existing treatment regimen for individual persons. It is not indicated as an alternative therapy to replace conventional medicines or any other treatments prescribed by a healthcare provider. When using Sinulex® Forte Capsules for maintenance therapy, it is specifically indicated for the purposes of maintaining healthy levels of its key ingredients and is not indicated for alternative maintenance therapy. It is not indicated as a cure-all or monotherapy for serious conditions because Sinulex® Forte Capsules are not intended (nor indicated) to diagnose, treat, prevent, or cure diseases. It is strictly indicated for symptomatic relief as a low-risk supportive supplement.

2. What you need to know before you use Sinulex® Forte Capsules.

Do not take Sinulex® Forte Capsules:

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Sinulex® Forte Capsules (listed in section 6).
- if you are on immunosuppressant medication since immunostimulant effects of Sinulex® Forte Capsules may interfere with the activity of immunosuppressants (see "Warnings and precautions").
- if you have a surgery or dental procedure scheduled, for at least two weeks prior.
- without consulting your healthcare provider if you have an existing treatment regimen.

Warnings and precautions

Special care should be taken with Sinulex® Forte Capsules:

- if you are already on immunosuppressant medication because of the immunostimulant properties of the active ingredients in Sinulex® Forte Capsules.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

Children

Do not give Sinulex® Forte Capsules to children who are below the age of 6 years because it is unlikely to be safe. Do not attempt to modify the composition of the capsule. The recommended dosages are specifically calculated to be safe for persons above the age of 6 years only. Keep out of the reach of children.

Other medicines and Sinulex® Forte Capsules

Always tell your health care provider if you are taking any other medicine. Other may interfere with or potentiate the effects of Sinulex® Forte Capsules and vice versa.

Sinulex® Forte Capsules with alcohol

We do not recommend that you use Sinulex® Forte Capsules with alcohol as this may only further impair the benefits that can be derived from the active substances.

Pregnancy and breastfeeding

Safety for use during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

No undesirable effects on driving and using machines have been reported with Sinulex® Forte Capsules. It is not always possible to predict to what extent a medicine may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which a medicine affects them.

Sinulex® Forte Capsules contains the following excipients:

- Maize starch
- Microcrystalline cellulose
- Magnesium stearate
- Silicone dioxide

3. How to take Sinulex® Forte Capsules.

Do not share medicines prescribed for you with any other person. Always take Sinulex® Forte Capsules exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

- The usual dose is 1 capsule, 3 times daily for adolescents over 12, adults, and the elderly; and is the maximum recommended daily and/or total dose.
- The usual dose is 1 capsule, 2 times daily for children over 6 years of age; and is the maximum recommended daily and/or total dose.
- Each dose must be taken or given with a sufficient quantity of liquid (preferably a glass of room temperature water) to ensure safe and proper swallowing/intake of each capsule.
- Only take this product orally.

If you take more Sinulex® Forte Capsules than you should

- you may experience gastrointestinal discomfort.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Sinulex® Forte Capsules

- then do not exceed the maximum recommended daily and/or total dose; and
- do not use a double dose to make up for forgotten individual doses.

4. Possible side effects.

Sinulex® Forte Capsules can have side effects. Not all side effects reported for Sinulex® Forte Capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Sinulex® Forte Capsules, please consult your health care provider for advice.

If any of the following happens, stop taking/using Sinulex® Forte Capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects and could be signs of an allergic reaction or hypersensitivity to Sinulex® Forte Capsules. You may need urgent medical attention or hospitalization.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Sinulex® Forte Capsules.

5. How to store Sinulex® Forte Capsules.

Store all medicines out of reach of children. Store in a cool, dry place at temperatures of 59-77° F, equivalent to 15-25° C, and with ambient humidity between 35% and 65%. Do not refrigerate or freeze. Store in the original package or container. Protect from direct sunlight and moisture. Do not use it after the expiry date stated on the label. Do not use Sinulex® Forte Capsules if you notice abnormal appearance or unpleasant odor, as the product may be expired or was improperly stored. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems. Please recycle the empty containers.

6. Contents of the pack and other information.

What Sinulex® Forte Capsules contains

The active substances are as listed at the start of this leaflet. The other ingredients are listed as excipients (see section 2) in this leaflet.

What Sinulex® Forte Capsules looks like and contents of the pack

Sinulex® Forte Capsules may come in blister packs of 10 capsules or zip-lock sachets of 3 capsules each, as the primary packaging. Sinulex® Forte Capsules has a capsule dosage form with a specific appearance: Capsule, hard gelatin, white and yellow, 21.6mm lock length, and no markings. The carton acts as the secondary packaging for storage, also showing the proper labeling.

Holder of Certificate of Registration

Tara Pharmaceuticals (Pty) Ltd

36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

Application number

DCFS-db4f9a

Act 101/1965

Access to corresponding Professional Information

<https://www.tarapharmaceuticals.com/items>



Afrikaans

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSSTATUS:

S0

Sinulex® Forte Kapsules

Sterkte
391.81 mg per kapsule

Farmaseutiese vorm
Kapsule, harde gelatien, solied orale

Aktiewe bestanddele

| | |
|--------------------------------|---------|
| Vitamiën C | 300 mg |
| Peperwortelwortel | 50 mg |
| Sinksulfaat heptahidraat | 21.8 mg |
| Pelargonium wortel | 20 mg |
| Vitamiën D3 | 7.5 µg |

Suikervry:

- Bevat nie versoeters nie.

Hierdie produk is 'n Komplimentêre Medisyne (Kategorie D33.7); en word geïdentifiseer volgens sy dissipline as 'n Kombinasie Produk; which is not registered by the Owerheid.

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir die kwaliteit, veiligheid of beoogde gebruik daarvan nie.

Lees hierdie hele pamflet noukeurig deur omdat dit belangrike inligting vir u bevat

Sinulex® Forte Kapsules is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n ligte siekte kan behandel of jou gesondheid kan handhaaf. Maar jy moet nog steeds Sinulex® Forte Kapsules ernstig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Misken moet jy dit weer lees.
- Moenie Sinulex® Forte Kapsules deel met enige ander persoon nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies nodig het.
- U moet 'n dokter sien as u simptome vererger of nie na 7 dae verbeter nie.

Wat is in hierdie pamflet

1. Wat Sinulex® Forte Kapsules is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy Sinulex® Forte Kapsules gebruik.
3. Hoe om Sinulex® Forte Kapsules te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Sinulex® Forte Kapsules te stoor.
6. Inhoud van die pak en ander inligting.

1. Wat Sinulex® Forte Kapsules is en waarvoor dit gebruik word.

Sinulex® Forte Kapsules ondersteun die immuunstelsel om allergene, verkoues, griep en sinusitis te hanteer vir beter algemene gesondheid. As gevolg van die aktiewe bestanddele word Sinulex® Forte Kapsules slegs aangedui vir terapeutiese gebruik vanaf die ouderdom van 6 jaar en ouer. Hierdie aktiewe bestanddele word benut vir simptomiese verligting van sinusdruk, sinusopeenhoping, post-nasale drup, verkoues en griepsimptome, deur die respiratoriese en immuunstelsels te ondersteun. Die aktiewe bestanddele kan ook die immuunfunksie ondersteun van diegene wat asimptomaties is as 'n laerisiko-gesondheidsaanvulling en kan gebruik word om gesonde vlakke van Vitamiën C, Vitamiën D3 en Sink te handhaaf. Dit is 'n gesondheidsaanvulling wat belangrike immunomodulatoriese en immunostimulerende eienskappe bevat en kan gebruik word om die respiratoriese kanaal en die paranasale sinusse ondersteun. Sinulex® Forte Kapsules word aangedui vir selfadministrasie as 'n laerisiko-gesondheidsaanvulling, hoewel slegs 'n gesondheidsorgverskaffer dit kan aandui as 'n byvoeglike behandeling vir 'n bestaande behandelingsregime vir individuele persone. Dit word nie aangedui as 'n alternatiewe terapie om konvensionele medisyne of enige ander behandelings wat deur 'n gesondheidsorgverskaffer voorgeskryf word, te vervang nie. By die gebruik van Sinulex® Forte Kapsules vir onderhoudsterapie word dit spesifiek aangedui vir die doeleindes van die handhawing van gesonde vlakke van sy sleutelbestanddele en word nie vir alternatiewe instandhoudingsterapie aangedui nie. Dit word nie aangedui as 'n geneesmiddel of monoterapie vir ernstige toestande nie omdat Sinulex® Forte Kapsules nie bedoel (of aangedui) is om siektes te diagnoseer, te behandel, te voorkom of te genees nie. Dit word streng aangedui vir simptomiese verligting as 'n lae-riisiko ondersteunende aanvulling.

2. Wat jy moet weet voordat jy Sinulex® Forte Kapsules gebruik.

Moenie Sinulex® Forte Kapsules neem:

- as jy hipersensitief (allergies) is vir die aktiewe stowwe, of enige van die ander bestanddele Sinulex® Forte Kapsules (gelys in afdeling 6) nie.
- as jy op immuunonderdrukkende medikasie is nie sedert die aktiewe bestanddele vervat in Sinulex® Forte Kapsules 'n immunostimulerende effek het (sien 'Waarskuwings en voorsorgmaatreëls').
- as u 'n operasie of tandheelkundige prosedure geskeduleer het nie, vir ten minste twee weke voor dit.
- sonder om u gesondheidsorgverskaffer te raadpleeg as u 'n bestaande behandelingsregime het nie.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Sinulex® Forte Kapsules:

- as jy reeds op immuunonderdrukkende medikasie is as gevolg van die immunostimulerende eienskappe van die aktiewe bestanddele.
- wanneer jy swanger is of borsvoed omdat veiligheid tydens swangerskap en laktasie nie vasgestel is nie.

Kinders

Moenie Sinulex® Forte Kapsules aan kinders onder die ouderdom van 6 jaar gee nie, want dit is onwaarskynlik dat dit veilig sal wees. Moenie probeer om die samestelling van die kapsules te verander nie. Die aanbevole dosisse word spesifiek bereken om slegs veilig te wees vir persone bo die ouderdom van 6 jaar. Hou buite bereik van kinders.

Ander medisyne en Sinulex® Forte Kapsules

Sê altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne neem. Anders kan Sinulex® Forte Kapsules saam met ander medisyne inmengende of versterkte effekte hê.

Sinulex® Forte Kapsules met alkohol

Ons beveel nie aan dat u Sinulex® Forte Kapsules met alkohol gebruik nie, aangesien dit slegs die voordele wat uit die aktiewe bestanddele verkry kan word, verder kan benadeel.

Swangerskap en borsvoeding

Veiligheid vir gebruik tydens swangerskap en borsvoeding is nie vasgestel nie. As u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik van masjiene

Geen ongewenste effekte op die bestuur en gebruik van masjiene is aangemeld met Sinulex® Forte Kapsules nie. Dit is nie altyd moontlik om te voorspel in watter mate 'n medisyne die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate tot wat 'n medisyne hulle beïnvloed nie.

Sinulex® Forte Kapsules bevat die volgende ekspiënte:

- Mielië stysel
- Mikrokristallyneselulose
- Magnesiumsteraat
- Silikoondioksied

3. Hoe om Sinulex® Forte Kapsules te gebruik.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd Sinulex® Forte Kapsules presies soos beskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster jou vertel het. Raadpleeg u dokter, apteker of verpleegster as u nie seker is nie.

- Die gewone dosis is 1 kapsule, 3 keer per dag vir adolessente ouer as 12, volwassenes en bejaardes; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Die gewone dosis is 1 kapsule, 2 keer per dag vir kinders ouer as 6 jaar; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Elke dosis moet geneem of gegee word met 'n voldoende hoeveelheid vloeistof (verkieklik 'n glas kamertemperatuurwater) om veilige en behoorlike sluk/innam van elke kapsule te verseker..
- Neem slegs hierdie produk mondelings.

As jy meer Sinulex® Forte Kapsules neem as wat jy moet

- jy kan gastro-intestinale ongemak ervaar.
- In die geval van oordosering, raadpleeg u dokter of apteker. Indien een nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om Sinulex® Forte Kapsules te gebruik

- moet nie die maksimum aanbevole daaglikse en/of totale dosis oorskry nie; en moenie 'n dubbele dosis gebruik om op te maak vir vergete individuele dosisse nie.

4. Moontlike nuwe-effekte.

Sinulex® Forte Kapsules Kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Sinulex® Forte Kapsules gerapporteer word, word in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige gevolge ervaar terwyl jy Sinulex® Forte Kapsules neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om Sinulex® Forte Kapsules te neem/gebruik en vertel u dokter onmiddellik of gaan na die ongevallen-afdeling by u naaste hospitaal:

- 'swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haaf',
- 'uitslag of jeuk',
- 'floute'

Dit is alles baie ernstige nuwe-effekte en kan tekens wees van 'n allergiese reaksie of hipersensitieweit vir Sinulex® Forte Kapsules. Misken het u dringende mediese hulp of hospitalisasie nodig.

As u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u jou dokter of apteker in kennis stel.

Verslagdoening van nuwe-effekte

As u nuwe-effekte kry, praat dan met u dokter, apteker of verpleegster. U kan ook nuwe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies gevind word:

<https://www.sahpra.org.za/Publications/Index/8>. Deur

verslagdoening van nuwe-effekte, kan jy help om meer inligting oor die veiligheid van Sinulex® Forte Kapsules.

5. Hoe om Sinulex® Forte Kapsules te stoor.

Stoor alle medisyne buite bereik van kinders. Stoor in 'n koel, droë plek by temperatuur van 59-77° F, gelykstaande aan 15-25° C, en met omgewingsvochtigheid tussen 35% en 65%. Moenie verkoel of vries nie. Stoor in die oorspronklike pakket of houer. Beskerm teen direkte sonlig en vog. Moenie dit gebruik na die vervaldatum wat op die etiket aangedui is nie. Moenie Sinulex® Forte Kapsules gebruik as jy 'n abnormale voorkoms of onaangename reuk opmerk nie, aangesien die produk moontlik verval het of onbehoorlik gestoor was. Gee alle ongebruikte medisyne aan u apteker terug. Moenie ontslae raak van ongebruikte medisyne in dreine of rioelstelsels nie. Herwin asseblief die leë houers.

6. Inhoud van die pak en ander inligting.

Wat Sinulex® Forte Kapsules bevat

Die aktiewe bestanddele is soos gelys aan die begin van hierdie pamflet. Die ander bestanddele word gelys as ekspiënte (sien afdeling 2) in hierdie pamflet.

Hoe Sinulex® Forte Kapsules lyk en inhoud van die pak

Sinulex® Forte Kapsules kan kom in blasiepakkes van 10 kapsules of ritsslotsakkies van 3 kapsules elk, as die primêre verpakking. Sinulex® Forte Kapsules het 'n kapsule dosis vorm met 'n spesifieke voorkoms: Kapsule, harde gelatien, wit en geel, 21.6mm slot lengte, en geen merke. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Edms) Bpk
36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

Aansoeknommer

DCFS-db4f9a
Wet 101/1965

Toegang tot ooreenstemmende Professionele Inligting

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